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Self treatment with one of three self selected, ultramolecular homeopathic medicines for the prevention of upper respiratory tract infections in children. A double-blind randomized placebo controlled trial

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Aims
Homeopathic medicines are frequently purchased over the counter (OTC). Respiratory complaints are the most frequent reason for such purchases. Children with upper respiratory tract infection (URTI) are frequent users of homeopathy. This study investigates the effect of self treatment with one of three self selected ultramolecular homeopathic medicines for the prevention of childhood URTI.

Methods
A double-blind randomized parallel group placebo controlled trial was carried out in 251 children below the age of 10 years, recruited by post from those previously diagnosed with URTI when attending a casualty department. The children were randomly assigned to receive either placebo or ultramolecular homeopathic medicines in C-30 potency (diluted 10^{-60}) administered twice weekly for 12 weeks. Parents chose the medicine based on simplified constitutional indications for the three medicines most frequently prescribed by Norwegian homeopaths for this group of patients. The main outcome measure relates to the prevention of new episodes of URTI measured with median total symptom score over 12 weeks.

Results
There was no difference in the predefined primary outcome between the two groups ($P = 0.733$). Median URTI scores over 12 weeks in the homeopathic medicine group were 26.0 (95% confidence interval (CI) 16.3, 43.7) and for placebo 25.0 (95% CI 14.2, 38.4). There was no statistical difference between the two groups in median number of days with URTI symptoms or in the use of conventional medication/care.

Conclusions
In this study there was no effect over placebo for self treatment with one of three self selected, ultramolecular homeopathic medicines in preventing childhood URTI. This can be due to the lack of effect of the highly diluted homeopathic medicines or the process of selection and type of medicines.

Introduction

Homeopathic medicines are often used for upper respiratory tract infections (URTI), both over the counter (OTC) and individualized preparations prescribed after consultation with a homeopath. It appears that the OTC use of homeopathic medicines is increasing [1] and two studies have found that OTC products are most frequently used for respiratory complaints [2, 3]. Homeopathic medicines could be well suited for self-treatment, if they are efficacious, due to their apparent low or lack of toxicity [4]. Homeopathic medicines sold OTC are usually in lower dilution (material doses) and also frequently contain two or more homeopathic medicines in one preparation (combination medicines) [1].

Patients usually make their own choices when selecting an OTC homeopathic medicine based on 'popular' information [5]. Homeopaths on the other hand base their choice of the homeopathic medicine on the totality of the patient's symptoms and the patient's 'constitutional type' [6–8].

A Norwegian population study found that during the last year, 4 year old children with URTI visited physicians 10 times more frequently than other children [9]. These children are also frequent antibiotic users [10], a behaviour that might be modified if homeopathic medicine and homeopathic care were shown to be efficacious. Children under 10 years of age constitute 25% of all patients visiting Norwegian homeopaths [11], most frequently consulting for skin and respiratory complaints. The children are almost exclusively prescribed single homeopathic medicines in 'high' potencies (ultramolecular, where theoretically it is very unlikely that there are any molecules left of the original substance) [12].

There are very few studies evaluating individualized homeopathy for URTI in children. Two placebo controlled studies with individualized homeopathy for URTI in children have suggested a tendency, but found no statistically significant results for a specific effect from homeopathic medicines [13, 14]. An open randomized trial found that significantly more children with glue ear progressed to a normal tympanogram after receiving pragmatic homeopathic care than those receiving standard care [15], as well as a trend for more children to have improved hearing in the homeopathy group. A comparative nonrandomized trial of children with acute otitis media found faster resolution of pain and fewer recurrences in children who received treatment from an ENT specialist who prescribed homeopathy rather than conventional ENT specialists [16].

Based on this we considered it reasonable to conduct a study evaluating the specific effects of ultramolecular homeopathic medicine, by designing a study that mirrored homeopaths prescription without exposing the patients to a homeopathic consultation. The objective was to investigate whether self-treatment with self-selected homeopathic medicines was more efficacious than placebo in preventing URTI in children over a 12-week period without any interference by a homeopath.

Methods

Design

This trial was of double-blind, randomized parallel group placebo controlled design. It was performed according to the principles of the Helsinki declaration. The regional committee for medical ethics recommended the study and it was registered with the Norwegian Data Inspectorate. The study was carried out in Trondheim, a city with 150.000 inhabitants in the middle of Norway.

Patients

Children below 10 years of age who had been to a medical doctor for URTI were included in the study. URTI was defined as having a health problem that the consulting doctor gave an ICPC (International Classification of Primary Care) code of H01 (ear pain), H71 (acute otitis media), H72 (glue ear), H74 (chronic otitis media), R72 (streptococcal infection), R74 (URTI), R75 (sinusitis) or R76 (tonsillitis) [17]. The exclusion criteria were concomitant serious disease or daily use of medicines such as antibiotics, steroids (except in inhalers) and cytotoxic agents, and use of homeopathic medicines in the 3 months prior to inclusion.

The inclusion criteria were designed to recruit children who used the health services for their URTI and who could have an increased risk of getting an URTI in the future. The study focused on new episodes of URTI in children and recruited mainly children who had consulted the casualty department at the University Hospital. The trial took place over two periods to limit the study to the winter months which have a high incidence of URTI, September 2002 to June 2003 and January to June 2004. The hospital database was searched for patients meeting the inclusion criteria. Patients attending the casualty department between August 2002 and January 2003 were recruited to the first period, and those attending between February and December 2003 to the second period. In addition, folders were distributed in November 2002 to local child health centres and an advertisement was placed in the newspaper in January 2004. Patients were sent a letter with the informed consent form included for the parents to sign and return if they agreed to participate. All patients whose parents

returned the informed consent form and met the inclusion criteria were regarded as eligible, and were sent a baseline questionnaire. Those who returned this were entered into the study.

Randomization

Randomization was done by an independent trial service office that provided a randomization list. This list was sent to the manufacturer of the trial medication, Homeoden, Belgium. The trial medication was sent to the blinded study co-ordinator who distributed it consecutively to the participants as they were included.

Interventions

All participants were informed that they could use any treatment of their own choice except any other form of homeopathic medication apart from the trial medication and that they should seek help from their GP as needed.

In the baseline questionnaire, there was a description of the indications for three different homeopathic medicines, *Calcarea carb*, *Pulsatilla* and *Sulphur* (Table 1). The choice of medicines and the development and validation of these indications is described in detail elsewhere [18]: These medicines accounted for 60% of all prescriptions for children with URTI (data from a survey with 80 homeopaths/1097 patients [11]). The simplified constitutional indications were then developed in a group of five homeopaths and sent to 20 homeopaths. To evaluate the parents' choice of homeopathic medicines compared with the prescription by trained homeopaths, 11 randomly selected homeopaths and parents of 70 children participated. By using the simplified constitutional indications (Table 1), parents were able to choose the same homeopathic medicine as homeopaths prescribed for 55% (95% CI 43%, 67%) of children with URTI. There was excellent agreement between parent's choice and homeopath's prescription for the three medicines (Kappa 0.77, $P < 0.001$).

Table 1
English and Norwegian descriptions for the indications of the three homeopathic medicines most frequently prescribed by Norwegian homeopaths for children with upper respiratory tract infections (URTI). The descriptions are designed for parents

Calcarea carb	Pulsatilla	Sulphur
The child is calm, but quite headstrong. The child may be insecure toward new things. The child may be quite independent and likes to play alone. The child may perspire on the head and neck, especially when he/she has just fallen asleep. The child may have clammy feet. The child's stool, perspiration and breath may have a sour odour. When the child is ill there can be copious mucus and other discharges. The child may have a craving for eggs.	The child is mild and quite timid. The child usually does what it is told, and seldom makes a fuss. The child may be shy or sceptical toward strangers. The child likes to be cuddled and to sit on the lap. Instead of being angry and furious the child tends to be sad and clinging when it is upset. It is very easy to see if the child is happy or sorry.	The child may often be in charge when playing with other children. The child is quite determined and has its own opinions. The child may have an irritable disposition, especially when ill. The child can be messier than others of equal age. The child may suffer from soreness and redness around eyes and nose when having a cold. The child may be quite warm and doesn't need a lot of clothes. The child may be fond of highly seasoned food and food with a lot of flavours.
Barnet er rolig, men bestemt. Barnet kan være forsiktig i forhold til nye ting. Barnet kan være selvstendig og leker gjerne alene. Barnet kan svette på hodet og i nakken, spesielt når det har sovnet. Barnet kan være klam på beina. Avføring, svette og pust kan lukte surt. Når barnet er sykt kan det være mye snørr og slim. Barnet kan være glad i egg.	Barnet mildt og snilt. Det hører oftest etter når det blir bedt om noe. Barnet kan være litt tilbakeholden og skeptisk til fremmede mennesker. Barnet er glad i kos og i å sitte på fanget. Barnet blir oftere lei seg og klengete enn rasende og sint. Det er veldig lett å se forskjell på glede og sorg hos barnet.	Barnet tar gjerne ledelsen når det leker med andre barn. Barnet er bestemt og har egne meninger. Barnet kan være irritabel, spesielt ved sykdom. Barnet kan søle mer enn jevnaldrende. Barnet kan plages av rødhet og sårhet rundt nese og øyne ved forkjølelse. Barnet kan være varmblodig og trenger lite klær. Barnet kan være glad i mat med krydder og sterk smak.

Calcarea carb is made of the inside of oyster shell. Pulsatilla is made from the plant wind flower (Pulsatilla pratensis). Sulphur is made from sulphur.

The parents were asked to read the three indications in Table 1, called description 1, 2 and 3, and then answer the following questions: 'Which indication do you think resembles the way your child is most of the time?' and 'How well do you actually think that the indication you have chosen resembles your child?' (Answering categories were; 'very well', 'well', 'neither', 'bad' and 'very bad'). They were then sent the selected study medicine, or a placebo, at the beginning of the study (Figure 1).

The manufacturer, Homeoden Belgium, made the medicines according to the German Homeopathic Pharmacopoeia [19] and prepared a separate box for each of the three medicines. Each box consisted of bottles numbered consecutively, with placebo and homeopathic medicines allocated according to the randomization list. A C30 potency was used, which means that the active substance is diluted 1/100 in a water/alcohol solution in 30 successive steps, giving a dilution of 10^{-60} of the starting substance. As this is below the Avogadro number [20], it is frequently described as ultramolecular as none of the original substance is theoretically present in the medication given to the patient. Between each dilution the preparation is succussed vigorously. The final preparation is impregnated on lactose pills and tumbled dry. The alcohol evaporates during the tumbling process, and there is no taste or smell of alcohol on the pills. The pills were packaged dry in vials containing 10 g of pills. The placebos were lactose pills and indistinguishable from the homeopathic medicines in package, look, taste and smell.

The parents were instructed to give their children two pills two days a week for 12 weeks. In addition they were instructed to give one pill up to once every hour if the child had an acute episode of URTI, but to reduce the intake of pills if the URTI was mild or when there was an improvement.

To minimize the interaction, the parents of the children were told that they could contact the study coordinator if they had any questions, otherwise the only contact was written information sent by mail.

Outcome measures

Daily patient diaries were used as the main outcome measure and were completed by the child's parents. Diaries were used to avoid the intrusive nature of assessment, to mirror real life as much as possible and because the parents can best assess their child's health [21, 22]. The study lasted for 12 weeks for each of the participants and to improve compliance the participants were sent and returned diaries every fourth week.

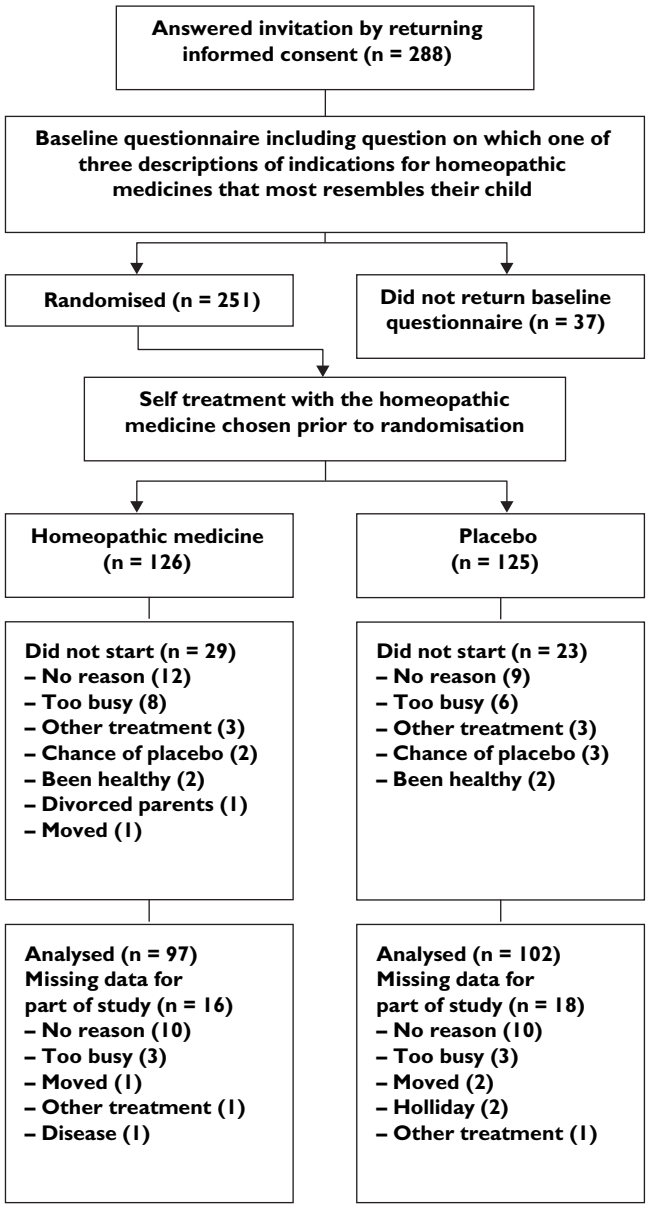

Figure 1
Flow of participants through the trial

The diary asked whether the child had been ill with URTI, had other illness, used antibiotics, used painkiller/antipyretic drugs, visited a medical doctor, whether someone had been absent from work due to the child's illness and whether the child had taken the study medication (measure of adherence to treatment). The parents were told to 'Regard the child to be ill if he/she is more ill than he/she usually is' and that an URTI was present when the child is 'ill with complaints in ear/nose/throat'. Otherwise, the parents were instructed to regard any complaint as 'other illness'. On the days when the child was ill with URTI, the parents filled in

Table 2
The symptom diary to be used on days where the parents judged their child to be ill with URTI

	Number of points		
Symptoms	0	1	2
Fever (°C)	<38°C	38–39°C	>39°C
Pain	No	Complains	Scream
Mood	Normal	Bad	
Appetite	Normal	Diminished	
Energy	Normal	Diminished	
Sleep	Normal	Disturbed	
Discharge	Normal	Increased	
Obstruction of nose	Normal	Increased	
Cough	Normal	Increased	

The parents were asked to score according to how the child has been during the day. The symptoms constitute a symptom score that can reach a maximum of 11 points each day.

a separate symptom diary based on a score previously used by Jacobs *et al.* for assessing homeopathic treatment of children with otitis media [14]. This scale also emphasizes general symptoms that may be of importance to homeopaths. The difference between the score used in this study and the one used by Jacobs *et al.* was that 'Other URTI symptoms' was replaced with 'discharge', 'nasal obstruction' and 'cough' (Table 2). Nine symptoms could be recorded with a daily possible total score range of 0–11. The calculation of total symptom score is done by adding the score for each day. The score is zero if the child does not have an URTI. The scale has not previously been used in a trial of URTI, so to evaluate whether it captured the general condition of the child, it was validated against a question on general wellbeing scored as normal, deteriorated or very bad on days with URTI.

Sample size

There were no previous data using the main outcome measure on which to base the sample size calculation. It was decided in line with other rigorous pragmatic studies [21], that the smallest difference worth detecting was a 20% reduction in number of days with URTI. It was hypothesized that nontreated children might have three episodes of URTI, each lasting 5 days, giving an expected 15 days with URTI for those in the placebo group and 12 days for those receiving homeopathic medicine during the 12 week study period. The standard deviation was estimated to be a doubling of the difference (6 days). The power calculation was done using 80% power and a 5% significance level resulting in an estimated 63 patients in each group. Because the parents could only chose between three homeopathic medicines, it was anticipated that around half of the patients would receive a homeopathic medicine that would be different from that chosen by a homeopath. Because this could 'dilute' the effect, it was decided to double the number of patients in both groups. The aim was to recruit a minimum of 135 patients in each group.

Analysis

Confirmatory testing of the main outcome measure is based on intention to treat, with all patients who started the study included in the analysis. There were no data for those who were randomized but did not start the study. Predefined primary outcome was median total symptom score for URTI during the 12 weeks (Table 2). Secondary outcome was median number of days with URTI symptoms. Values for the missing days for those who were lost to follow up, were replaced with the average value for the period they participated. Continuous data were tested using a nonparametric test (Mann–Whitney, two tailed) due to the nonparametric nature of the data. Pearson's chi square test was used for categorical data. As most data were skewed and had outliers, distribution is described with median and 95% confidence intervals (CI) for the median. All data were analyzed using SPSS for Windows version 12.0.1. The calculation of 95% CI was done with STATA version 8.0.

Results

Two hundred and eighty-eight patients returned the informed consent form and were eligible to participate. Two hundred and fifty-one of these returned the baseline questionnaire and were randomized. Of these, 96 participated in the first period and 155 in the second period. Two hundred were recruited from the casualty department, 34 from the advertisement in the local newspaper and 17 from the folders distributed to the child's health clinics. A total of 52 (20.7%) patients either did not return any data (diary) or withdrew after having been randomized, leaving 102 in the placebo group and 97 in the homeopathic medicine group (Figure 1).

Thirty-four patients were lost to follow up and did not return data for the whole study, 16 in the homeopathic medicine group and 18 in the placebo group. One participant in the homeopathic medicine group withdrew due to being hospitalized with osteomyelitis 1 week after starting the study. No one reported an adverse

reaction as a reason for dropping out, but one in each group self-withdrew because they wanted to begin another treatment. Those lost to follow up in both groups tended to have higher symptom scores and more days with URTI than those who completed the study, when missing values were replaced with the average value for the period in which they participated, although this was not statistically significant. Overall, the groups were comparable at baseline for demographic variables and health history (Table 3).

Outcome

The correlation between total symptom score derived from the symptom diaries and general well-being was highly significant with a correlation coefficient of 0.728 ($P < 0.001$, Spearman's rank correlation). In both groups the children had taken the study medication on a median of 24 days ($P = 0.663$), indicating good adherence to the treatment.

There was no difference between groups for the primary outcome, the median daily symptom score. The score for the homeopathic medicine group was 26 (95% CI 16, 44) and for the placebo group 25 (95% CI 14, 38) ($P = 0.733$) (Table 4). The median number of days where the parents judged their child to be ill with URTI symptoms was 9 (95% CI 4, 12) days in the homeopathic medicine group and 8 (95% CI 6, 9) days in the placebo group ($P = 0.531$). The median number of episodes with URTI lasting three days or more was 1 in both groups ($P = 0.927$).

There was no difference between the groups in the number of children who had 1 or more days with URTI symptoms (Table 5). There was no statistical difference in the use of conventional medication (antibiotics and painkillers) and visits to a medical doctor (Tables 4 and 5). Four (3.9%) in the placebo group and nine (9.3%) in the homeopathic medicine group self reported having an adverse effect, which were all mild and transient ($P = 0.126$).

A subanalysis was completed on trial participants who scored their selected medicine description as 'matching' their child very well or well (Table 3). These groups were comparable at baseline, displaying the same baseline characteristics as the whole sample. The median daily symptom score for the homeopathic medicine ($n = 50$) group was 29 (95% CI 15, 47) and for the placebo ($n = 59$) group 35 (95% CI 16, 40) ($P = 0.932$). The median number of days when the parents judged their child to be ill with URTI symptoms was 9 (SD 4–12) days in the homeopathic medicine group and 9 (95%

Table 3
Characteristics of children who started the study. Values are either number of children (percentage %) or mean for the whole group (standard deviation SD)

Characteristic	Homeopathic medicine ($n = 97$)	Placebo ($n = 102$)
Mean age (SD)	3.6 (2.5)	3.2 (2.4)
Boys (%)	56 (57.7)	53 (52.0)
Very good or good global health judged by parents (%)	75 (77.3)	84 (82.4)
Children with frequent colds (%)	58 (60.0)	58 (56.9)
Mean number of ear infection (SD)	2.6 (3.5)	2.8 (3.2)
Mean number of throat infection (SD)	1.7 (3.0)	1.7 (3.4)
Mean number with bronchitis (SD)	0.3 (0.7)	0.3 (0.7)
Mean number of pneumonias (SD)	0.2 (0.6)	0.6 (3.2)
Had grommets inserted (%)	7 (7.2)	13 (12.7)
Had tonsillectomy (%)	4 (4.1)	8 (7.8)
Mean number of days with painkiller/antipyretic last 3 months (SD)	4.9 (4.9)	4.2 (3.8)
Mean number of courses with antibiotics last 3 months (SD)	0.8 (1.0)	0.8 (0.9)
Mean number of visits to medical doctor in the previous 3 months (SD)	1.7 (1.5)	2.0 (1.9)
Non smoking household (%)	84 (86.6)	97 (95.1)
Mean number of children in the household (SD)	2.0 (0.9)	2.0 (0.9)
Attending nursery or school (%)	75 (77.3)	71 (69.6)
Parents confident in homeopathy (%)	34 (35.1)	35 (34.3)
Selected homeopathic medicine (%); *Calcarea carb*, *Pulsatilla*, *Sulphur*	40 (41.2)	41 (40.2)
	37 (38.1)	40 (39.2)
	20 (20.6)	21 (20.6)
Indication for homeopathic medicine resembled child very well/well	50 (51.5)	59 (57.8)

Table 4
Effect of treatment with ultramolecular homeopathic medicine (n = 97) or placebo (n = 102) in prevention of URTI in children. Median for whole group (95% confidence interval (CI))

Outcome measure	Homeopathic medicine Median (95% CI)	Placebo Median (95% CI)	*P* value*
Total symptom score	26 (16.3, 43.7)	25 (14.2, 38.4)	Z = 0.341, *P* = 0.733
Days with URTI	9 (4, 12)	8 (6, 9)	Z = 0.627, *P* = 0.531
Days with antibiotic	0 (0, 0)	0 (0, 0)	Z = 0.352, *P* = 0.725
Days with painkiller/antipyretic	1 (0, 2)	0 (0, 1)	Z = 1.191, *P* = 0.234
Visits to medical doctor	0 (0, 1)	0 (0, 0)	Z = 0.946, *P* = 0.344
Days with other illness	1 (0, 2)	0 (0, 2)	Z = 0.303, *P* = 0.762
Days with noises from chest	0 (0, 0)	0 (0, 0)	Z = 0.547, *P* = 0.585
Days with work absence due to ill child	0 (0, 1.7)	0 (0, 0.4)	Z = 0.842, *P* = 0.400

**Mann-Witney (nonparametric) test.*

Table 5
Effect of treatment with ultramolecular homeopathic medicine (*n* = 97) or placebo (*n* = 102) in prevention of URTI in children. Number of children (%)

Number of children who	Homeopathic medicine *n* (%)	Placebo *n* (%)	*P* value*
Had days with URTI	81 (83.5)	81 (79.4)	$\chi^2 = 0.550$, *P* = 0.458
Had days with other illness	53 (54.6)	49 (48.0)	$\chi^2 = 0.867$, *P* = 0.352
Used antibiotics	19 (19.6)	17 (16.7)	$\chi^2 = 0.286$, *P* = 0.593
Used painkiller/antipyretic	51 (52.6)	44 (43.1)	$\chi^2 = 1.776$, *P* = 0.183
Consulted a medical doctor	41 (42.3)	35 (34.3)	$\chi^2 = 1.333$, *P* = 0.248
Had parents with work absence when ill	48 (49.5)	41 (40.2)	$\chi^2 = 1.735$, *P* = 0.188

**Pearson's chi square test.*

CI 7, 12) days in the placebo group ($P = 0.877$). There was no significant difference between homeopathy and placebo for the other variables.

Discussion

There was no statistically significant different effect of self treatment with one of three self selected, ultramolecular homeopathic medicines compared with placebo used for the prevention of upper respiratory tract infections in children in this study.

This study represents an innovative investigative model that separates the process of consulting a homeopath from the specific effects of the homeopathic medicine while at the same time mirroring the prescription of the homeopaths. We carefully piloted and validated the method for selecting homeopathic medicines to reflect common homeopathic practice in Norway for conditions that are seen frequently by homeopaths. This process has made it possible to use the usual homeopathic medicines that homeopaths in Norway prescribe for individual children with URTI, without the patients/parents being exposed to a homeopathic consultation.

Although the model used for selecting the homeopathic medicines was evaluated prior to the study [18], the model is proxy for the treatment given by homeopaths in their everyday practice. Therefore there is a possibility that the patients received a homeopathic medicine that was not appropriate for them. Parents could only choose between three different homeopathic medicines, something that is not in line with the individualization required in homeopathic care. Neither the medicine nor the dosage could be changed during the

course of the study. This is what normally occurs in OTC treatment although not in normal homeopathic practice where medicines may be changed by the homeopath. It may also be argued that the homeopathic medicines were administered too frequently but although this was not tested in a pilot, the dosage was decided after consultations with several homeopaths. Finally, because this study builds on how homeopaths in Norway prescribe homeopathic medicines, it may not reflect the 'real world' OTC use of homeopathic medicines.

To minimize the contact with the participants, it was decided not to have a recruitment meeting with the patients or to phone them during the study. This could explain the relatively large number of patients not starting the study even though they had returned both their informed consent and baseline questionnaire.

The diaries were designed to capture the parents' judgement of the condition of the child. This was done to mirror everyday life where parents are the ones who decide if their child is ill or not. The symptom diary used to calculate the main outcome was chosen as it captures the general condition of children during episodes of URTI and is easy and simple for parents to complete. The validity of the symptom diary was tested against a question on the child's general well being and showed good correlation. This indicates that it measured what it was intended to measure. The reliability of the symptom diary was not formally tested. Because any bias in the parents' judgement is equally split between the groups, this does not influence the results.

In the pretrial validation study there was a tendency for parents to think that the indication for the homeopathic medicines had a better resemblance to their child if they had chosen the same medicine which the homeopath had prescribed [18]. Therefore, the sub analysis was completed with this group of patients. Although there was a trend for those in the homeopathic medicine group to do better than the placebo group, it was not significant and does not alter the main findings of this study.

The calculated pretrial sample size for this study is smaller than that suggested by other similar homeopathic studies. Jacobs *et al.* calculated, based on their results, that 235 subjects per group were needed to evaluate the effect of homeopathic medicine on acute otitis media [14], and Harrison *et al.* calculated that 135 subjects per group were needed for a definitive trial on homeopathic care for children with glue ear [15]. Based on the result from the sub analysis with a difference in symptom score of 6 (SD 52.5) in favour of homeopathic medicine, 1297 subjects in each group who thought the indications for the homeopathic medicines resembled their child 'very well' or 'well' would be needed using this study methodology to demonstrate a specific effect from ultramolecular homeopathic medicines. The total number to be recruited, given that about 50% thought the indications resembled their child well, would then be over 5000 subjects. The clinical value of this could be questioned.

This study was designed to operate without any direct interaction between the parents/patients and homeopaths thus minimizing nonspecific practitioner-effects. The results of this study suggest that these effects may be the main or even the only effects relevant to the clinical outcome for homeopathy in this group of patients.

To our knowledge this is the first randomized double-blind placebo controlled trial of self-treatment with self-selected homeopathic medicines. In spite of the promise of previous studies [13, 14], our investigation reports that there are no specific effects of the three self selected ultramolecular homeopathic medicines used in this study to prevent URTI in Norwegian children.

What is already known

Homeopathy is frequently used for self treatment (OTC)
There are no studies on the effect of self treatment with self selected homeopathic medicines
Children with URTI are frequently treated by homeopaths

What this study adds

This study found no effect over placebo of self treatment with one of three self selected ultramolecular homeopathic medicines for prevention of upper respiratory tract infections in children. This could be due to the lack of effect of the highly diluted homeopathic medicines or the process of selection and type of medicines.

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